IN THE CLAIMS

Please cancel claims 2, 4-6, 10 and 12 without prejudice to or disclaimer of the subject matter contained therein. Please amend claims 1, 3, 7, 8, 11 and 14 as outlined in Appendices E ("marked up" copy) and F (clean copy) attached herewith.

REMARKS

Claims 1-6, 8, 10-11, 13 and 14 are currently pending in the present application. Claims 2, 4-6, 10 and 12 have been canceled without prejudice to or disclaimer of the subject matter contained therein. Claims 1, 3, 7, 8, 11 and 14 have been amended in the expectation that the amendments will place this application in condition for allowance. The amendments do not introduce new matter within the meaning of 35 U.S.C. § 132. Accordingly, entry of the amendments is respectfully requested.

1. Objection to the Specification

The specification has been objected to because it ``does not contain an abstract of the disclosure as required by 37 CFR 1.72(b).''

In response to this objection, applicants enclose herewith an Abstract of the Disclosure in Appendices A (``marked up'' copy) and B (clean copy). Its entry is respectfully requested.

The Official Action also states that ``The brief description of the drawings for Figures 1 and 2 should be amended to reflect the views, i.e., Fig. 1A and 1B.''

In response to this objection, applicants enclose herewith

Appendices C (``marked up'' copy) and D (clean copy), which contain amended brief descriptions of the drawings of Figures 1A, 1B, 2A and 2B. Its entry is respectfully requested.

2. Objection of claims 3, 5, 6, 8 and 10-12

In the Official Action, the Examiner has objected to claims 3, 5, 6, 8 and 10-12 for various reasons.

Claims 5, 6, 10 and 12 have been cancelled, rendering the objection of these claims moot. Regarding claims 3, 8 and 11, applicants have amended these claims to overcome the objections.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the objection of pending claims 3, 8 and 11.

3. Rejection of claims 1-7 under 35 U.S.C. §101

The Official Action states that claims 1-7 are rejected under 35 U.S.C. §101. In particular, the Official Action states:

> Claims 1-7 are rejected because the claimed invention us directed to non-statutory subject matter. The claimed invention fails to reflect the hand of man in that it is directed to a product of nature. The claims should be amended to reflect an isolated peptide.

Applicants have cancelled claims 2 and 4-6, rendering the rejection of these claims moot. Regarding claims 1, 3 and 7, applicants have amended these claims to reflect ``an isolated peptide".

Accordingly, applicants respectfully request that the Examiner

reconsider and withdraw the rejection of these claims.

4. Rejection of claims 1, 4, 8 and 10-14 under 35 U.S.C. §112, 1st paragraph

The Official Action states that claims 1, 4, 8 and 10-14 are rejected under 35 USC §112, 1st paragraph. Applicants respectfully traverse this rejection.

The Official Action states the following, in relevant part:

> ``Claims 1 and 14 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.
>
> Claim 1 is drawn to peptides which bind antibodies that are found in elevated levels in body fluids of schizophrenic patients. However, the specification only discloses 5 such peptides, as disclosed at p. 14, which bind to antibodies elevated in schizophrenic patients.
>
> While the artisan would recognize that any 5 mer of these peptides maybe capable of reacting with such antibodies, the artisan is not apprised nor does the specification teach alternative peptide sequences which would react with autoantibodies which are elevated in schizophrenic patients.
>
> Whereas the instant specification provides a detailed description of a number of species of peptides, the description is not sufficient to provide for those unrelated peptide epitopes which can not be predicted, are not disclosed but which are instantly claimed.''

Applicants respectfully point out to the Examiner that the instant claims are not drawn to the enzymes that bind to the

diagnostic peptides, but are drawn to the diagnostic peptides themselves, i.e. SEQ ID NOs 1-8. These SEQ ID NOs have been adequately described in Table 2. In fact, the Examiner has stated in the Official Action on page 6, last sentence of the 2nd full paragraph, that "Table 2 is supportive of a written description of SEQ ID NOs 1-8 which sequences are within the scope of the invention."

The Official Action goes on to state the following, in relevant part:

> ``Claims 1, 4, 8 and 10-14 are rejected under 35 USC §112, first paragraph, because the specification, while being enabling for contiguous epitope segments of the disclosed peptides and for peptides of SEQ ID NOs 1-8 which are capable of binding to platelet derived autoantibodies which are found to be elevated levels in schizophrenic patients, does not reasonably provide enablement for alternative, unrelated peptide sequences, for peptides which bind antibodies elevated in body fluids of schizophrenic patients, for peptides of the subgenus which bind antibodies capable of binding to SEQ ID NO:2, but are not capable of binding for example to SEQ ID NOs 9-14 or for methods of assaying and kits for the detection and diagnosis of schizophrenia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants respectfully traverse this rejection. Although applicants appreciate the Examiner's comments regarding that the specification is enabling for the contiguous epitope segments of the disclosed peptides and for the peptides of SEQ ID NOS 1-8, applicants respectfully point out to the Examiner that the claims of the instant application are drawn to the diagnostic peptides

themselves, i.e. SEQ ID NOs 1-8 and not the contiguous epitope segments that bind to the diagnostic peptides.

In view of this, applicants respectfully point out to the Examiner that the presently pending claims hereby bear a reasonable correlation with the scope of enablement as required by *In re Fisher*.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection of these claims.

5. Rejection of claims 1-3 and 14 under 35 U.S.C. §102(b) as being anticipated by Ishiguro et al.

The Official Action states that claims 1-3 and 14 are rejected under 35 USC 102(b). In particular, the Official Action states, in relevant part:

> ``Claims 1-3 and 14 are rejected under 35 USC 102(b) as being anticipated by Ishiguro et al.
>
> Ishiguro teaches enolase peptides as disclosed in Figure 7, which peptides share a 5-mer segment with instant SEQ ID NO: 2, in particular, the amino acid sequence `QIKTG'. Thus the peptides would be recognized by the artisan as an immunogen and epitope capable of binding antibodies that bind SEQ ID NO: 2 and which are found in elevated levels in body fluids of schizophrenic patients.
>
> It is noted that MPEP 2111.02 discusses the weight of the preamble, specifically the weight given to a preamble statement reciting purpose or intended use as in claim 14. Claim 14 recites a kit `for use in the diagnosis of schizophrenia'. However, the preamble fails to structurally delimit the kit by the recitation of a specific product, apparatus or manipulative step which

distinguishes the claimed kit from the prior art reagents and methods of analysis. The preamble is not granted patentable weight with respect to the claim because the prior art reagents and methods are similarly capable of performing the intended use as recited in the preamble. Thus, the reference teachings anticipate the claimed peptides and kit as claimed."

Claim 2 has been cancelled without prejudice or disclaimer to the subject matter contained therein, rendering the rejection of this claim moot. As to claims 1, 3 and 14, applicants respectfully traverse this rejection.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP 2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

The presently claimed invention relates to an isolated peptide which binds antibodies that are found in elevated levels in body fluids of schizophrenic patients, wherein said isolated peptide comprises a sequence of the formula: $X_1LVVGLCTX_2QIKTGX_3CX_4$. The Ishiguro reference teaches the 5-mer segment "QIKTG".

The Ishiguro reference clearly fails to anticipate the

presently pending claims because it does not teach ``each and every element'' of the claimed invention as required by *Verdegaal Bros. v. Union Oil Co. of California*. Applicants are claiming an isolated peptide which binds antibodies that are found in elevated levels in body fluids of schizophrenic patients, wherein said isolated peptide comprises a sequence of the formula: X_1LVVGLCTX_2QIKTGX_3CX_4. Ishiguro does not disclose an isolated peptide of this formula but merely discloses a 5-mer.

Additionally, Ishiguro does not teach the binding characteristics of the presently claimed invention. Claims 1 and 3 are drawn to ``an isolated peptide which binds antibodies that are found in elevated levels in body fluids of schizophrenic patients''. Ishiguro does not disclose the treatment of schizophrenic patients, nor does it disclose the binding characteristics of the peptides which binds the antibodies that are found in elevated levels in the body fluids of schizophrenic patients.

Further, should the Examiner maintain this rejection after recognizing the structural differences of Ishiguro and the presently claimed invention, applicants would appreciate an appropriate explanation from the Examiner how the Ishiguro reference would be considered an enabling reference based on a mere 5-mer sequence, but applicant's previous claim 1 was alleged as not enabling based applicant's disclosure of a much larger 16+-mer

sequence.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1, 3 and 14.

6. Rejection of claims 1-3 under 35 U.S.C. §102(b) as being anticipated by Russell et al.

The Official Action states that claims 1-3 and 14 are rejected under 35 USC 102(b). In particular, the Official Action states, in relevant part:

> ``Claims 1-3 are rejected under 35 USC 102(b) as being anticipated by Russell et al.
>
> Russell et al. teach chicken skeletal-muscle enolase peptide with an amino acid sequence which shares a 7-mer sequence with instant SEQ ID NO 2, see in particular residues of 1-7 of SEQ ID NO 2 corresponding with residues 383-389 of chicken enolase. The peptide is immunogenic as it is greater than 3 amino acids in length and shares at least a single epitope with SEQ ID NO 2 as the shared sequences is at least 4-6 amino acids in length. Therefore the peptide is necessarily capable of binding to an antibody capable of binding to SEQ ID NO 2 and the reference teachings anticipate the claimed invention.''

Claim 2 has been cancelled without prejudice or disclaimer to the subject matter contained therein, rendering the rejection of this claim moot. As to claims 1 and 3, applicants respectfully traverse this rejection.

The presently claimed invention relates to an isolated peptide which binds antibodies that are found in elevated levels in body

fluids of schizophrenic patients, wherein said isolated peptide comprises a sequence of the formula: $X_1LVVGLCTX_2QIKTGX_3CX_4$. The Russell et al reference teaches a chicken skeletal muscle enolase peptide with a 7-mer amino acid sequence.

The Russell et al. reference clearly fails to anticipate the presently pending claims because it does not teach ``each and every element'' of the claimed invention as required by *Verdegaal Bros. v. Union Oil Co. of California*. Applicants are claiming an isolated peptide which binds antibodies that are found in elevated levels in body fluids of schizophrenic patients, wherein said isolated peptide comprises a sequence of the formula: $X_1LVVGLCTX_2QIKTGX_3CX_4$. Russell et al. do not disclose an isolated peptide of this formula but merely disclose a 7-mer.

Additionally, Russell et al. do not teach the binding characteristics of the presently claimed invention. Claims 1 and 3 are drawn to ``an isolated peptide which binds antibodies that are found in elevated levels in body fluids of schizophrenic patients''. Russell et al. do not disclose the treatment of schizophrenic patients, nor do they disclose the binding characteristics of the peptides which binds the antibodies that are found in elevated levels in the body fluids of schizophrenic patients.

Further, should the Examiner maintain this rejection after

recognizing the structural differences of the teachings of the Russell et al. reference and the presently claimed invention, applicants would appreciate an appropriate explanation from the Examiner how the Russell et al. reference would be considered an enabling reference based on a mere 7-mer sequence, but applicant's previous claim 1 was alleged as not enabling based on applicant's disclosure of a much larger 16+-mer sequence.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1 and 3.

7. Allowable Subject Matter

The Official Action states that claims 5-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants thank the Examiner for this indication of allowable subject matter. However, based on the foregoing amendments, applicants believe that they have placed this application in condition for allowance.

Applicants also respectfully point out to the Examiner that previously non-elected claim 7 has not been cancelled and is therefore, currently pending in this application. Claim 7 has been amended to be dependent from claim 1, thereby making the subject

matter "inseparable therefrom and thus linking together the inventions otherwise divisible". See MPEP 809.03. Claims 1 and 7 have thus been "linked" together with a common core in accordance with applicant's right to a broader claim scope. See MPEP 809.04.

Accordingly, applicants respectfully request examination of claim 7 and withdrawal of the restriction requirement as to the linked inventions.

CONCLUSION

In view of the foregoing, applicants respectfully request the Examiner to reconsider and withdraw the objections and rejections of the pending claims.

If the Examiner has any questions or wishes to discuss this application, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

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Date: 15 Oct. 2002

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PATENT
Attorney Docket No. 24390

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

SHINITZKY et al.

Serial No.: 09/647,457 Art Unit: 1647

Filed: November 29, 2000 Examiner: S. Turner

For: **ASSAY FOR THE DIAGNOSIS OF SCHIZOPHRENIA BASED ON A NEW PEPTIDE**

Appendix B

Please insert the following "Abstract of the Disclosure" into the captioned application as outlined in the following "clean" copy of the Abstract.

ABSTRACT OF THE DISCLOSURE

The invention concerns peptides which bind antibodies that are found in elevated levels in body fluids of schizophrenic patients and are found at a lower level or not found at all in body fluids of non-schizophrenic individuals. Using a computerized program, the antigenic epitope of the peptides of the invention is predicted as having a core of hydrophobic amino acids which is surrounded by positively charged amino acids. The peptides of the invention are useful in the diagnosis of schizophrenia in an individual.

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Filed: November 29, 2000 Examiner: S. Turner

For: **ASSAY FOR THE DIAGNOSIS OF SCHIZOPHRENIA BASED ON A NEW PEPTIDE**

Appendix A

Please insert the following "Abstract of the Disclosure" into the captioned application as outlined in the following "marked up" copy of the Abstract.

ABSTRACT OF THE DISCLOSURE

The invention concerns peptides which bind antibodies that are found in elevated levels in body fluids of schizophrenic patients and are found at a lower level or not found at all in body fluids of non-schizophrenic individuals. Using a computerized program, the antigenic epitope of the peptides of the invention is predicted as having a core of hydrophobic amino acids which is surrounded by positively charged amino acids. The peptides of the invention are useful in the diagnosis of schizophrenia in an individual.

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Filed: November 29, 2000 Examiner: S. Turner

For: **ASSAY FOR THE DIAGNOSIS OF SCHIZOPHRENIA BASED ON A NEW PEPTIDE**

Appendix D

Please amend the specification as outlined herein below in this "clean" copy of the specification:

At page 10, lines 17-24, please delete the current text and replace with the following text:

"Fig. 1A is a graphical representation showing binding activity of the Peptide I4 having SEQ ID NO: 2 to PAAs prepared from samples obtained from schizophrenic patients. The peptide having SEQ ID NO: 9 was used as a negative control.

Fig. 1B is a graphical representation showing binding activity of the Peptide I4 having SEQ ID NO: 2 to PAAs prepared from samples obtained from non-schizophrenic individuals. The peptide having SEQ ID NO: 9 was used as a negative control.

Fig. 2A is a graphical representation showing binding activity of peptide I4 (SEQ ID NO: 2) to plasma samples obtained from schizophrenic patients. The peptide having SEQ ID NO: 9 was used as a negative control.

Fig. 2B is a graphical representation showing binding activity of peptide I4 (SEQ ID NO: 2) to plasma samples obtained from non-schizophrenic individuals. The peptide having SEQ ID NO: 9 was used as a negative control."

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For: **ASSAY FOR THE DIAGNOSIS OF SCHIZOPHRENIA BASED ON A NEW PEPTIDE**

Appendix C

Please amend the specification as outlined herein below in this "marked up" copy of the specification:

At page 10, lines 17-24, please delete the current text and replace with the following text:

"Fig. 1A is a graphical representation showing binding activity of the Peptide I4 having SEQ ID NO: 2 to PAAs prepared from samples obtained from schizophrenic patients. The peptide having SEQ ID NO: 9 was used as a negative control.

Fig. 1B is a graphical representation showing binding activity of the Peptide I4 having SEQ ID NO: 2 to PAAs prepared from samples obtained from non-schizophrenic individuals. The peptide having SEQ ID NO: 9 was used as a negative control.

Fig. 2A is a graphical representation showing binding activity of peptide I4 (SEQ ID NO: 2) to plasma samples obtained from schizophrenic patients. The peptide having SEQ ID NO: 9 was used as a negative control.

Fig. 2B is a graphical representation showing binding activity of peptide I4 (SEQ ID NO: 2) to plasma samples obtained from non-schizophrenic individuals. The peptide having SEQ ID NO: 9 was used as a negative control."

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SHINITZKY et al.

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Filed: November 29, 2000 Examiner: S. Turner

For: **ASSAY FOR THE DIAGNOSIS OF SCHIZOPHRENIA BASED ON A NEW PEPTIDE**

Appendix F

Please cancel claims 2, 4-6, 10 and 12 without prejudice to or disclaimer of the subject matter contained therein. Please amend claims 1, 3, 7, 8, 11 and 14 as outlined in the following "clean" copy of the claims.

1) An isolated peptide which binds antibodies that are found in elevated levels in body fluids of schizophrenic patients, wherein said isolated peptide comprises a sequence of formula I:

$$X_1LVVGLCTX_2QIKTGX_3CX_4$$

wherein X_1 is selected from the group consisting of SGETEDTFIAD, IAD, AD, D, and a bond/hydrogen;

X_2 is selected from the group consisting of C, G, and P;

X_3 is selected from the group consisting of AP, and PA; and

X_4 is selected from the group consisting of R, and a bond/hydrogen.

3) An isolated peptide according to claim 1, which binds antibodies that are capable of binding to a peptide, wherein said isolated peptide is selected from the group consisting of:

a. SGETEDTFIADLVVGLCTGQIKTGAPCR (SEQ ID NO. 1);

b. LVVGLCTCQIKTGPAC (SEQ ID NO. 2);

c. IADLVVGLCTGQIKTGAPCR (SEQ ID NO. 3);

d. ADLVVGLCTGQIKTGAPCR (SEQ ID NO. 4);

e. DLVVGLCTGQIKTGAPCR (SEQ ID NO. 5);

f. LVVGLCTGQIKTGAPCR (SEQ ID NO. 6);

g. LVVGLCTGQIKTGPACR (SEQ ID NO. 7); and

h. LVVGLCTPQIKTGPACR (SEQ ID NO. 8).

7) An isolated peptide according to claim 1 which binds antibodies that are found in elevated levels in body fluids of schizophrenic patients, said isolated peptide comprising at least one antigenic epitope, said epitope having a cyclic three dimensional structure consisting of a hydrophobic core and a positively charged extension.

8) An assay for the diagnosis of schizophrenia in an individual, comprising the following steps:

a. obtaining a sample from said individual being a blood sample, a platelet-containing fraction thereof, or a fraction containing platelet-associated antibodies (PAA) shed from the platelets;

b. contacting said sample with an isolated peptide according to claim 1;

c. determining the level of binding of said peptide to said sample, a level higher than the binding level of said peptide to a sample from non-schizophrenic

16 individuals indicating that said individual has a high likelihood of having schizophrenia.

17 11) An assay according to claim 8, wherein the isolated peptide in step (b) is an isolated peptide selected from the group consisting of

a. SGETEDTFIADLVVGLCTGQIKTGAPCR (SEQ ID NO. 1);
b. LVVGLCTCQIKTGPAC (SEQ ID NO. 2);
c. IADLVVGLCTGQIKTGAPCR (SEQ ID NO. 3);
d. ADLVVGLCTGQIKTGAPCR (SEQ ID NO. 4);
e. DLVVGLCTGQIKTGAPCR (SEQ ID NO. 5);
f. LVVGLCTGQIKTGAPCR (SEQ ID NO. 6);
g. LVVGLCTGQIKTGPACR (SEQ ID NO. 7); and
h. LVVGLCTPQIKTGPACR (SEQ ID NO. 8).

18 14. A kit for use in the diagnosis of schizophrenia comprising:

a. a support comprising one or more isolated peptides in accordance with claim 1 immobilized onto it;
b. an anti-human immunoglobin antibody or fragment thereof which maintains the binding characteristics of the whole antibody, said antibody or fragment thereof conjugated to a detectable marker;
c. reagents required for carrying out the assay, and;
d. instructions for use.

PATENT
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For: **ASSAY FOR THE DIAGNOSIS OF SCHIZOPHRENIA BASED ON A NEW PEPTIDE**

Appendix E

Please cancel claims 2, 4-6, 10 and 12 without prejudice to or disclaimer of the subject matter contained therein. Please amend claims 1, 3, 7, 8, 11 and 14 as outlined in the following "marked-up" copy of the claims.

1) (Amended) [A] An isolated peptide which binds antibodies that are found in elevated levels in body fluids of schizophrenic patients, wherein said isolated peptide comprises a sequence of formula I:

$$X_1LVVGLCTX_2QIKTGX_3CX_4$$

wherein X_1 is selected from the group consisting of SGETEDTFIAD, IAD, AD, D, and a bond/hydrogen;
X_2 is selected from the group consisting of C, G, and P;
X_3 is selected from the group consisting of AP, and PA; and
X_4 is selected from the group consisting of R, and a bond/hydrogen.

3) (Twice Amended) [A] An isolated peptide according to claim 1, which binds antibodies that are capable of binding to a peptide, wherein said isolated peptide is selected from the group consisting of:

a. SGETEDTFIADLVVGLCTGQIKTGAPCR (SEQ ID NO. 1);

b. LVVGLCTCQIKTGPAC (SEQ ID NO. 2);

c. IADLVVGLCTGQIKTGAPCR (SEQ ID NO. 3);

d. ADLVVGLCTGQIKTGAPCR (SEQ ID NO. 4);

e. DLVVGLCTGQIKTGAPCR (SEQ ID NO. 5);

f. LVVGLCTGQIKTGAPCR (SEQ ID NO. 6);

g. LVVGLCTGQIKTGPACR (SEQ ID NO. 7); and

h. LVVGLCTPQIKTGPACR (SEQ ID NO. 8).

7) (Amended) [A] An isolated peptide according to claim 1 which binds antibodies that are found in elevated levels in body fluids of schizophrenic patients, said isolated peptide comprising at least one antigenic epitope, said epitope having a cyclic three dimensional structure consisting of a hydrophobic core and a positively charged extension.

8) (Twice amended) An assay for the diagnosis of schizophrenia in an individual, comprising the following steps:

a. obtaining a sample from said individual being a blood sample, a platelet-containing fraction thereof, or a fraction containing platelet-associated antibodies (PAA) shed from the platelets;

b. contacting said sample with [a] an isolated peptide [having the amino acid sequence of SEQ ID No. 2] according to claim 1;

c. determining the level of binding of said peptide to said sample, a level higher than the binding level of said peptide to a sample from non-schizophrenic individuals indicating that said individual has a high likelihood of having schizophrenia.

11) (Amended) An assay according to claim 8, wherein the isolated peptide in step (b) is [a] an isolated peptide selected from the group consisting of

a. SGETEDTFIADLVVGLCTGQIKTGAPCR (SEQ ID NO. 1);
b. LVVGLCTCQIKTGPAC (SEQ ID NO. 2);
c. IADLVVGLCTGQIKTGAPCR (SEQ ID NO. 3);
d. ADLVVGLCTGQIKTGAPCR (SEQ ID NO. 4);
e. DLVVGLCTGQIKTGAPCR (SEQ ID NO. 5);
f. LVVGLCTGQIKTGAPCR (SEQ ID NO. 6);
g. LVVGLCTGQIKTGPACR (SEQ ID NO. 7); and
h. LVVGLCTPQIKTGPACR (SEQ ID NO. 8).

14. (Twice amended) A kit for use in the diagnosis of schizophrenia comprising:

a. a support comprising one or more isolated peptides in accordance with claim 1 immobilized onto it;
b. an anti-human immunoglobin antibody or fragment thereof which maintains the binding characteristics of the whole antibody, said antibody or fragment thereof conjugated to a detectable marker;
c. reagents required for carrying out the assay, and;
d. instructions for use.